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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,230	04/02/2004	Victor I. Chornenky	1004.013	3048

7590 04/27/2007

Law Offices
P.O. Box 386353
Bloomington, MN 55438

EXAMINER	
GILBERT, ANDREW M	
ART UNIT	PAPER NUMBER
3767	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/817,230	CHORNENKY ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/23/2007 has been entered.

Acknowledgments

2. This office action is in response to the reply filed on 2/23/2007.

3. In the reply, claims 1 and 5 were amended and claims 9-14 were cancelled.

4. Thus, claims 1-8 are pending for examination on the merits.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Weiss (6402734). Weiss discloses a minimally invasive therapeutic agent delivery system (Fig 4) comprising a reservoir (12) comprising a therapeutic agent (col 4, ln 14); an elongate

probe (6) having a passage therein, the probe configured to conform at least in part to the curvature of the eye (col 3, lns 50-64) and has a proximal probe end (Fig 3) and a distal probe end (Fig 3) including a distal probe opening (Fig 3); a therapeutic agent delivery apparatus (4) comprising a needle having a sharp tip (4, Fig 3) configured to pierce the sclera to a predetermined depth, and the said needle being fluidly connected to said reservoir (Fig 4; col 3, lns 50-64; col 4, lns 11-21) and configured to be disposed within said passage (Fig 3) and movable between a retracted inoperative position within said probe (col 3, lns 50-64) and an extended operational position (col 3, lns 50-64), wherein movement of said delivery apparatus from the inactive to the operational position causes said needle to pierce the sclera to a predetermined position (Fig 3; col 3, lns 50-64) and enables the therapeutic agents to be dispensed from said reservoir through said needle into the eye (col 3, lns 50-64; col 4, lns 11-21; col 5, lns 23-38); a handle (1a) attached to said probe proximal end (Fig 1); the reservoir being attached to said handle (Fig 4); the therapeutic agent delivery apparatus comprises an elongate needle (4; col 3, lns 21-32).

7. Claims 1-6, 8 rejected under 35 U.S.C. 102(e) as being anticipated by Paques et al (2002/0087128). Paques et al discloses a minimally invasive therapeutic agent delivery system (Fig 1) comprising a reservoir (10) comprising a therapeutic agent (Fig 4, [0020, 0039, 0041,0058]); an elongate probe (2) having a passage therein, the probe configured to conform at least in part to the curvature of the eye (Fig 2, 4) and has a proximal probe end (2p) and a distal probe end (2d) including a distal probe opening

(Fig 1, 2d); a therapeutic agent delivery apparatus (Fig 1) comprising a needle having a sharp tip (4, 4a) configured to pierce the sclera to a predetermined depth (wherein the Examiner notes that the device is fully capable of piercing to a predetermined depth under control of the user), and the said needle being fluidly connected to said reservoir (Fig 1, 4, [0040-0041) and configured to be disposed within said passage (Fig 1) and movable between a retracted inoperative position within said probe ([0021, 0023, 0028-0030, 0039-0044, 0058]) and an extended operational position ([0021, 0023, 0028-0030, 0039-0044, 0058]), wherein movement of said delivery apparatus from the inactive to the operational position causes said needle to pierce the sclera to a predetermined position (Fig 1, [0021, 0023, 0028-0030, 0039-0044, 0058]) and enables the therapeutic agents to be dispensed from said reservoir through said needle into the eye ([0021, 0023, 0028-0030, 0039-0044, 0058])); a handle (2a, 2p) attached to said probe proximal end (2a, 2p, Fig 1, 4); the reservoir being attached to said handle (Fig 1, [0041]); the therapeutic agent delivery apparatus comprises an elongate needle (4);and said probe includes a probe positioning portion (2d) at said distal probe end; the elongate probe configured to conform at least in part to the curvature of the eye (Fig 1, 4, [0021, 0023, 0028-0030, 0039-0044, 0058]) and the probe distal end having an eye-surface engaging surface (2d, Fig 1, 4), the probe passage including a portion conforming to the surface of the eye (2d, Fig 1, 4) and a portion that angles toward the eye such that said distal probe opening is in said eye-surface engaging surface (4, 2d, Fig 1, 4).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paques et al in view of Flaherty et al (6544230). Paques et al discloses the invention substantially as claimed except for expressly disclosing wherein said passage bends said needle when said needle is moved from its retracted to its extended position. Flaherty et al teaches that it is known to have a elongate member (12) having a passage bend a piercing needle (30, 30d, Fig 7) when said needle is moved from its retracted to its extended position (Fig 10a, 10f) for the purpose of controlling and enhanced aiming of the needle member so it will remain inside a preferred place or acceptable penetration zone as it is advanced (col 11, lns 24-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the piercing needle as taught by Paques et al with the piercing needle having a resilient curved distal portion formed of a resilient material as taught by Flaherty et al for the purpose of controlling and enhanced aiming of the needle member so it will remain inside a preferred place or acceptable penetration zone as it is advanced (col 11, lns 24-67).

Response to Arguments

10. Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant's arguments filed 2/23/2007 against the the 35 USC 102(e) rejection of claims 1-4 to Weiss have been fully considered but they are not persuasive.

12. The Applicant argues against the 35 USC 102(e) rejection of claims 1-4 to Weiss by stating:

> i. Weiss does not disclose the new amendments to claim 1 that now define the delivery apparatus as having a needle with a sharp tip configured to pierce the sclera to a pre-determined depth. (Remarks, pg 5, paragraph 2)

13. In response to the Applicant's argument that (i), the Examiner notes that Weiss explicitly discloses a needle (4) with a sharp tip (4, Fig 3) that is fully capable of piercing the sclera at a predetermined depth (Fig 3, col 3, lns 50-64). The Examiner notes that in order to be given patentable weight, a functional recitation must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. See *In re Fuller*, 1929 C.D. 172; 388 O.G. 279. In the instant case, the recitation configured to pierce the sclera to a predetermined depth does not recite specific structure allowing or enabling the needle to only pierce a certain depth. The device of Weiss is fully capable of piercing a predetermined depth at the sclera through operations of the user. The Examiner suggests incorporating claim limitations detailing

structure of the Applicant's invention that allows or enables the needle to only pierce a predetermined depth of the sclera. The rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER